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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/872,466	05/31/2001	Adonis Stassinopoulos	Cerus-5100	3008

7590 04/22/2003

CERUS CORPORATION  
2525 Stanwell Drive # 300  
Concord, CA 94520

EXAMINER

WITZ, JEAN C

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 04/22/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/872,466

Applicant(s)

STASSINOPOULOS, ADONIS

Examiner

Jean C. Witz

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) 15,25 and 43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14,16-24,26-42 and 44-55 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election of the species of beta-alanine, N-(acridin-9-yl), 2[bis(2-chloroethyl) amino]ethyl ester and N-hydroxy succinimide butanoic acid monomethoxy polyethylene glycol in Paper No. 5 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

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Claims 15, 25, and 43 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species.

### ***Claim Rejections - 35 USC § 112***

Claims 28-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 28-37 recite a "A method of using the composition of claim \_\_\_\_" followed by transitional phrasing. The claims are indefinite as they fail to recite an object of the claimed method. A method claim where the body of the claim mandates use of a composition is inherently a method of using the composition; many method claims are methods of use of compositions. However, there must be an object to the use; otherwise, the claim is vague and indefinite.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-14, 16-24, 26-42, and 44-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scott et al. (5,908,624) in view of Harris et al. (5,672,662) combined with Cook et al. (WO 9830545).

The claims recite compositions of red blood cells and methods of treating red blood cells where the red blood cells are treated to substantially inactivate pathogens by contact with a compound having an affinity for nucleic acids and an effector group that reacts to bond covalently to the nucleic acid and wherein the red blood cells have been reacted with an antigen masking compound.

The compound that has an affinity for nucleic acids is beta-alanine, N-(acridin-9-yl), 2[bis(2-chloroethyl) amino]ethyl ester and the antigen masking compound is N-hydroxy succinimide butanoic acid monomethoxy polyethylene glycol.

Cook et al. in WO 9830545 discloses compounds and methods for inactivating pathogens in red blood cell preparations using compounds that have an affinity for nucleic acids and effector groups. Beta-alanine, N-(acridin-9-yl), 2[bis(2-chloroethyl) amino]ethyl ester is disclosed as a compound that has an affinity for nucleic acids and mustard mustard group equivalents are taught as effector groups. In effect, the pathogen inactivation step of the claims is fully disclosed by the reference. However,

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the reference does not disclose further treatment of the blood composition to mask antigens on the red blood cells.

Scott et al. disclose the treatment of blood cell compositions with an antigen masking compound. The antigen masking compound is disclosed as polyethylene glycol and derivatives thereof such as monomethoxypolyethylene glycol. The compound may contain a linker such as taught in col. 7 of the reference including N-hydroxysuccinimide. In col. 7, the patent teaches that the invention is not intended to be limited to particular examples and that any linker molecule capable of both covalently attaching to the cell surface and to the non-immunogenic compound may be similarly used. However, N-hydroxy succinimide butanoic acid monomethoxy polyethylene glycol is not explicitly disclosed. Harris et al. is directed to specific PEG derivatives that are appropriate for use in biotechnical applications. N-hydroxy succinimide butanoic acid monomethoxy polyethylene glycol is explicitly disclosed as such a PEG derivative appropriate for use in biotechnical applications. Therefore, the disclosure of Scott motivates one of ordinary skill to select a monomethoxypolyethylene glycol masking agent with a N-hydroxysuccinimide linker such as N-hydroxy succinimide butanoic acid monomethoxy polyethylene glycol for antigen masking as disclosed by Scott et al.

Scott et al. teaches antigen masking such as claimed for red blood cell compositions that will be transfused. Cook et al. teaches pathogen inactivation such as claimed for red blood cell compositions that will be transfused. Since both pathogen inactivation and antigen masking to reduce immunogenicity are taught to be important to red blood cell compositions that are to be transfused, it would have been obvious to

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one of ordinary skill in the art at the time the invention was made to combine both processes in a treatment of red blood cells in order to produce a red blood cell composition of both reduced pathogenicity and immunogenicity. "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be prima facie obvious.). See also In re Crockett, 279 F.2d 274, 126 USPQ 186 (CCPA 1960) (Claims directed to a method and material for treating cast iron using a mixture comprising calcium carbide and magnesium oxide were held unpatentable over prior art disclosures that the aforementioned components individually promote the formation of a nodular structure in cast iron.); and Ex parte Quadranti, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992) (mixture of two known herbicides held prima facie obvious).

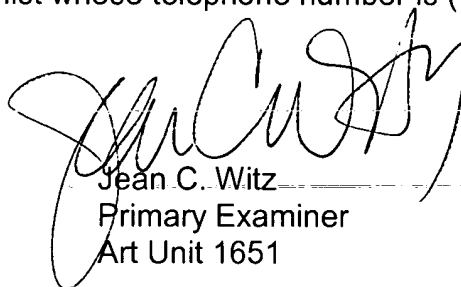
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jean C. Witz whose telephone number is (703) 308-3073. The examiner can normally be reached on 6:30 a.m. to 4:00 p.m. M-Th and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (703) 308-4743. The fax phone

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numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Jean C. Witz  
Primary Examiner  
Art Unit 1651

April 21, 2003